

July 18, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**RE: Docket Number 2005N-0147, Sprout Safety Public Meeting
70 Fed. Reg. 20852 (April 22, 2005)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) Produce Action Plan regarding the rulemaking to minimize foodborne illness associated with the consumption of sprouted seeds. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Summary

CSPI supports FDA's efforts to minimize foodborne illness associated with the consumption of sprouted seeds. The guidance documents issued by FDA in 1999, "Guidance for Industry: Reducing Microbial Food Safety Hazards for Spouted Seeds"¹ and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production"² represented important steps to addressing well documented hazards in sprout production. However, further actions, such as mandatory regulations, are needed. The continuance of sprout

¹ Guidance available at <http://vm.cfsan.fda.gov/~dms/sprougdl1.html>

² Guidance available at <http://vm.cfsan.fda.gov/~dms?sprougdl2.html>

outbreaks over the past five (5) years is evidence that preventative controls are needed by the seed and sprout industry. Until the agency subjects the entire sprout industry to tough, mandatory safety regulations, sprout safety will not improve across all segments of the industry.

In addition to the voluntary measures already put in place by the FDA guidance documents, FDA should adopt mandatory regulations requiring seed distributors to test and certify their seeds, and regulations requiring sprout growers to either use certified seeds or to test the irrigation water they use and the final product. Finally, if mandatory regulations are not adopted, the FDA should require mandatory labels on sprout packages warning consumers of the risks of consuming raw sprouts. These recommendations are discussed more fully below.

Mandatory Regulations Requiring Seed Distributors and Sprout Growers to Test Products Would Increase Safety of Sprouts

The FDA stated that since 1996, sprouts have accounted for 40% of all foodborne illness outbreaks associated with fresh produce.³ Since 1998, there have been twenty-six outbreaks associated with sprouts worldwide, twenty-five of which were directly linked to sprout growers in the United States and Canada.⁴ In 2001, thirty-two cases of *Salmonella* Kottbus infection were identified in California, Arizona, Colorado, and New Mexico. Of these, three required hospitalization. The subsequent outbreak investigation revealed that the outbreak was caused by alfalfa sprout consumption. Furthermore, it was determined that not only were the contaminated sprouts from a single sprouter, they were from a single seed lot that had been imported from

³ 70 Fed. Reg. 77, 20852-20854 (Apr. 22, 2005)

⁴ Rust, Bob, "Seed Handling & Distributing Systems, presentation at FDA public meeting, available at http://www.sproutnet.com/sprouting_seed_safety.htm.

Australia.⁵ Outbreaks associated with alfalfa sprouts continue to emerge. The FDA has reported that alfalfa sprouts were responsible for five (5) outbreaks in 2003 and two (2) outbreaks in 2004.⁶ Outbreaks associated with alfalfa sprouts have also been caused by *E. coli* O157:H7.⁷

A. Seed Distributors Should Certify Their Seeds

CSPI agrees with FDA that a critical step in preventing sprout-associated foodborne-illness outbreaks is a pathogen-elimination step for seeds. Outbreak data clearly shows that contaminated seeds are the primary cause of sprout outbreaks. Thus, steps are needed to reduce pathogens from seeds and to certify the seeds as safe so that sprout growers know they are purchasing safe, pathogen-free seeds.

As Bob Rust from International Specialty Supply stated in his talk at the May 2005 FDA public meeting on sprout safety, there are three ways that the seed industry can improve its record of shipping contaminated products to sprout growers.⁸ First, seed producers can grow, harvest, process, store and ship seed as though the seed were a food product.⁹ Secondly, seed producers can decontaminate seed that is destined for sprouting.¹⁰ And finally, seed producers can screen the seed for pathogens prior to shipping it out.¹¹ One such way to both ensure safe

⁵ See CDC, Outbreak of *Salmonella* serotype Kottbus Infections Associated with Eating Alfalfa Sprouts --- Arizona, California, Colorado, and New Mexico, February--April 2001, 51 *Morbidity and Mortality Weekly Report*, 7-9 (Jan. 11, 2002).

⁶ 70 Fed. Reg. 77, 20852-20854 (Apr. 22, 2005).

⁷ See "Consumers Advised of Risks Associated With Eating Raw and Lightly Cooked Sprouts," *FDA Talk Paper*, (Oct. 2, 2002) available at <http://www.cfsan.fda.gov/~lrd/tpsprout.htm>.

⁸ Rust, Bob, "Seed Handling & Distributing Systems, presentation at FDA public meeting, transcript available at <http://www.cfsan.fda.gov/~dms/sprotran.html>.

⁹ Id.

¹⁰ Id.

¹¹ Id.

seeds and to treat the seed as if it were a food product is to stop using seeds that have been grown for agricultural purposes. While this is a radical suggestion that would have industry-wide implications, the benefits would be astronomical. Under this approach, farms that supply seeds to sprout growers would exclusively route their seeds toward production of human food. Thus, the use of manure on seeds intended for human consumption would be banned. In addition, imported seeds would be banned unless the foreign seed grower could demonstrate that the seeds were produced under similarly strict guidelines.

Additionally, seeds intended for human consumption should be maintained in intact batches that are carried through the food production chain from the farm to the table. This would greatly improve recalls as the current practice of mixing batches of seeds makes trace-back nearly impossible. This will ensure that any problem seeds or sprouts produced from those seeds can be identified and quickly removed from the market.

According to the seed industry, seed screening - determining if the seed is contaminated prior to selling it for sprouting purposes - is a simple approach to risk reduction that is already being used by some segments of the sprout industry. When the seeds arrive at the plant, they are placed in a quarantined area and the bags are visually inspected for evidence of mouse droppings, holes, insect larvae, and bird droppings.¹² The bags are also placed under a black light for traces of urine.¹³ Then, a composite sample of seed is examined both under a magnifying glass and a microscope for indicators of contamination and to determine its fitness for human consumption.¹⁴ Finally, the entire sample is sprouted using commercial sprout

¹² Id.

¹³ Id.

¹⁴ Id.

pathogen reduction methods and the runoff water is collected and tested for both *Salmonella* and *E. coli* O157:H7.¹⁵ If any evidence of contamination is found, the seeds are not sold to sprout growers. One seed supplier has demonstrated that seed screening has many benefits and is very inexpensive.¹⁶ FDA should mandate that seed distributors conduct this kind of screening and certify their seeds as safe, in order to prevent contaminated seed lots from entering the market. This could significantly reduce the number of outbreaks associated with sprouts.

B. Sprout Growers Need to Ensure the Safety of their Sprouts

While seed distributors are one critical control point in sprout production, sprout growers also need to be regulated to ensure that the sprouts they are growing and selling to consumers are safe for consumption. While the FDA has issued guidance for sprout growers on testing spent irrigation water during sprout production, this testing should be mandatory for growers not using certified seed. This guidance, once made mandatory, should be clarified as well. First, the FDA should require that all samples be collected by personnel who have been trained and certified as able to collect samples aseptically. Secondly, FDA should require that sprouting facilities be required to have filtered air currents and should provide explicit instructions on how to run a positive control.

Finally, the FDA should require batch testing for *E. coli* O157:H7 and *Salmonella* and approve all sampling plans. However, FDA should not rely on microbial testing alone to ensure safety. FDA should develop a batch testing verification system in the context of a HACCP system for sprouts. While thorough irrigation water testing may be enough to regulate pathogens in sprouts at the grower/processor level, random testing of sprout batches should be mandatory to

¹⁵ Id.

provide an additional layer of protection since testing of irrigation water is not always 100% effective. This batch testing should be conducted by external, qualified, independent laboratories that are certified by the FDA to satisfy criteria outlined in regulations set by the agency.

Sprouts Should Be Labeled As High-Risk Foods

Because sprouts are the cause of such a high percentage of foodborne-illness outbreaks, the FDA, should it not adopt mandatory regulations, should require labels on all sprout containers. This warning would alert consumers that the product may not be safe to serve children, those with compromised immune systems, and elderly consumers. While the FDA has made numerous announcements warning consumers of the dangers of consuming sprouts, it has never mandated warning labels on sprouts.¹⁷ Previously, the FDA has implemented mandatory labels for several high-risk foods, such as unpasteurized apple cider and eggs, yet FDA continues to close their eyes to the lack of consumer knowledge of the significant health risks sprouts pose.

Effective package labeling would alert consumers to the risks of consuming sprouts. Labels should be concise, easy-to-read, prominently placed, and include a graphic symbol to aid consumers in identifying and remembering the risks. While this is a measure opposed by the sprout industry, it would be one of the most effective ways to communicate the dangers of sprouts to consumers. Should FDA choose not to implement a warning label system, FDA needs to adopt mandatory regulations, not guidance, to reduce pathogens in sprout seeds and sprouts.

¹⁶ Id.

¹⁷ See “Interim Advisory on Alfalfa Sprouts,” *FDA Talk Paper*, (Aug. 31, 1998) available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00890.html>; “Sprout Safety – High Risk Groups Warned: Don’t Eat Alfalfa Sprouts,” 32 *FDA Consumer Magazine*, November-December 1998, available at: http://www.fda.gov/fdac/departs/1998/698_upd.html; and “Consumers Advised of Risks Associated With Eating Raw and Lightly Cooked Sprouts,” *FDA Talk Paper*, (Oct. 2, 2002) available at <http://www.cfsan.fda.gov/~lrd/tpsprout.htm>.

Conclusion

FDA's guidance documents for sprouters were and continue to be an important step toward ensuring the safety of sprouts. However, the precautionary measures and testing programs set forth in the guidance documents will not be universally adopted by the sprout industry unless the agency makes its recommendations mandatory by undertaking the requisite regulatory process. Further delays in rulemaking are not warranted, and will only lead to additional sprout related illnesses and deaths. The agency has already held two (2) public meetings regarding sprout safety. FDA should immediately initiate that action, and should amend its recommendations as suggested above.

Respectfully submitted,

/s/ Amy E. McDonnell
Amy E. McDonnell
Staff Attorney, Food Safety Program

Caroline Smith DeWaal
Director, Food Safety Program